

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

PLANNED PARENTHOOD)
CINCINNATI REGION; PLANNED)
PARENTHOOD of GREATER)
CLEVELAND; PLANNED PARENTHOOD)
of CENTRAL OHIO; PRETERM;)
DR. ROSLYN KADE; AND DR. LASZLO)
SOGOR; on behalf of themselves, their staff,)
and their patients,)
c/o Alphonse A. Gerhardstein)
617 Vine St. #1409)
Cincinnati, OH 45202)

Plaintiffs,

v.

BOB TAFT, Governor of Ohio,
in his official capacity
30th Floor, 77 South High Street
Columbus, Ohio 43215-6117

and

JIM PETRO, Attorney General of Ohio,
in his official capacity;
State Office Tower 30 E. Broad Street 17th floor
Columbus, OH 43215-3428

and

MICHAEL K. ALLEN as Prosecuting
Attorney for Hamilton County, Ohio
and as representative of a class of all
Prosecuting Attorneys in Ohio.
230 E. Ninth St., Suite 4000
Cincinnati, OH 45202

Defendants.

**FIRST AMENDED COMPLAINT
(DEFENDANT CLASS ACTION)**

Case No. 1:04-CV-493

Judge Susan J. Dlott

Plaintiffs, by and through their attorneys, bring this first amended complaint against the above-named Defendants, their employees, agents, and successors in office, and in support thereof state the following:

I. INTRODUCTORY STATEMENT

1. This is a constitutional challenge brought pursuant to 42 U.S.C. § 1983 to obtain declaratory and injunctive relief relating to the State of Ohio's recently enacted H.B. 126 ("the Act"). The Act was signed by Ohio Governor Bob Taft June 24, 2004, and is scheduled to take effect on September 23, 2004, that being ninety days after the Act was signed by the Governor. A copy of the Act is attached as Exhibit A.

2. The Act regulates the use of the prescription drug mifepristone, a medication approved by the federal Food and Drug Administration (FDA) for the purpose of inducing abortions. Plaintiffs, four Ohio not-for-profit corporations and two physicians that provide a wide range of reproductive health services including abortion with mifepristone, claim that the Act is unconstitutionally vague; that the Act will violate their patients' right to bodily integrity; that the Act is unconstitutional because it lacks an exception to its restrictions where necessary to protect their patients' life or health; and that the Act imposes an undue burden on their patients' right to choose abortion, all in violation of the Fourteenth Amendment of the United States Constitution.

II. JURISDICTION AND VENUE

3. Jurisdiction is conferred on this Court by 28 U.S.C. § 1331, 1343(a)(3), and 1343(a)(4).

4. Plaintiffs' claim for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202, by Rules 57 and 65 of the Federal Rules of Civil Procedure, and by the general legal and equitable powers of this Court.

5. Venue is appropriate under 28 U.S.C. § 1391(b) because one of the Defendants resides in this judicial district and events giving rise to this action occur in this judicial district.

III. PARTIES

A. Plaintiffs

6. Plaintiff Planned Parenthood Cincinnati Region (PPCR), a non-profit corporation organized under the laws of the State of Ohio, operates eight health care centers located in and around Cincinnati, Ohio. PPCR provides a broad range of medical services to women and men in Ohio, including: family planning; complete gynecological annual examinations; cervical pap smears; counseling and treatment for sexually transmitted diseases; HIV testing; sonograms; pregnancy testing; referrals for diagnosis and treatment of genetic defects; medical abortion through the 9th week of pregnancy as measured from the first day of the woman's last menstrual period ("LMP"); and surgical abortion services through the 17th week LMP. Patients of PPCR, including patients seeking abortion, come from all across the state, as well as from Northern Kentucky and Eastern Indiana. PPCR sues on its own behalf, on behalf of its current and future medical staff, servants, officers, and agents who participate in activities that could subject them to criminal and civil liability under the Act (either directly or as accomplices), and on behalf of its patients.

7. Plaintiff Planned Parenthood of Greater Cleveland ("PPGC"), a non-profit corporation organized under the laws of the State of Ohio, operates five health care centers located in and around Cleveland, Ohio. PPGC provides a full range of reproductive health services to men and women, including: pregnancy diagnosis and counseling; contraceptive counseling; provision of all methods of contraception; HIV/AIDS testing and counseling; and testing, diagnosis, and treatment of sexually transmitted infections. PPGC provides medical abortions through 9 weeks LMP, and surgical abortions through 13 weeks LMP. PPGC sues on its own behalf, on behalf of its current and future medical staff, servants, officers, and agents who participate in activities that could subject them to criminal and civil liability under the Act (either directly or as accomplices), and on behalf of its patients.

8. Plaintiff Planned Parenthood of Central Ohio ("PPCO"), a non-profit corporation organized under the laws of the State of Ohio, operates seven health care centers located in the

central Ohio region. PPCO provides a full range of reproductive health services to men and women, including: pregnancy diagnosis and counseling; contraceptive counseling; provision of all methods of contraception; HIV/AIDS testing and counseling; and testing, diagnosis, and treatment of sexually transmitted infections. PPCO provides medical abortions through 7 weeks LMP, and surgical abortions through 13 weeks LMP. PPCO had been preparing to expand its medical abortion services to 9 weeks LMP, but suspended those preparations because of uncertainty as to the meaning and constitutionality of the Act. PPCO sues on its own behalf, on behalf of its current and future medical staff, servants, officers, and agents who participate in activities that could subject them to criminal and civil liability under the Act (either directly or as accomplices), and on behalf of its patients.

9. Plaintiff Preterm, a non-profit corporation organized under the laws of the State of Ohio, has operated a health care clinic in Cleveland, Ohio since 1974. Preterm provides a range of reproductive health services to its patients, including: family planning; emergency contraception and contraceptive counseling; pregnancy testing; sonograms; options counseling; referrals for treatment of sexually transmitted infections; medical abortion through 9 weeks LMP; and surgical abortion services through the 21st week LMP. Preterm also trains approximately 2-3 residents per year from University Hospitals, the Cleveland Clinic, and the MetroHealth Medical Center in abortion techniques. Patients of Preterm, including patients seeking abortions, come primarily from Northeast Ohio. Preterm sues on its own behalf, on behalf of its current and future medical staff, servants, officers, and agents who participate in activities that could subject them to criminal and civil liability under the Act (either directly or as accomplices), and on behalf of its patients.

10. Plaintiff Dr. Roslyn Kade is the medical director of Plaintiff Planned Parenthood Cincinnati Region. As medical director Planned Parenthood Cincinnati Region, Dr. Kade supervises the clinic's physicians and clinical staff and is responsible for the quality assurance of the medical services the clinic provides. In addition to her director duties, she provides medical

abortions at the clinic using an evidence-based regimen of mifepristone. Dr. Kade sues on her own behalf and on behalf of her patients seeking medical abortion.

11. Plaintiff Dr. Laszlo Sogor is the medical director of Plaintiff Planned Parenthood of Greater Cleveland. As medical director of Planned Parenthood of Greater Cleveland, Dr. Sogor supervises the clinic's physicians and clinical staff and is responsible for the quality assurance of the medical services the clinic provides. In addition to his director duties, he provides medical abortions at the clinic using an evidence-based regimen of mifepristone. Dr. Sogor sues on his own behalf and on behalf of his patients seeking medical abortion.

B. Defendants

12. Defendant Bob Taft is the Governor of the State of Ohio. In that capacity, he is empowered to ensure that the laws of the State are faithfully executed. *See* Ohio Const. Art. III, § 2. Defendant Taft is sued in his official capacity.

13. Defendant Jim Petro is the Attorney General of the State of Ohio. In that capacity, he is the chief legal officer for the State of Ohio. Among his duties is the requirement that he advise county prosecuting attorneys, when so requested. *See* Ohio Revised Code § 109.14. Defendant Petro is sued in his official capacity.

14. Defendant Michael K. Allen is the duly elected Prosecuting Attorney of Hamilton County, Ohio. In that capacity, he is charged with the responsibility of enforcing state criminal statutes including the Act. He is sued in his official capacity and as a representative of all prosecuting attorneys of the counties of Ohio.

15. Defendant Allen is sued, pursuant to Fed. R. Civ. P. 23(b)(1), as a representative of the class of all county prosecuting attorneys in Ohio.

16. The class of Ohio prosecuting attorneys is so numerous that joinder of all members is impracticable.

17. There are questions of law or fact common to the class.

18. The claims or defenses of the class representative are typical of the claims or defenses of the class.

19. Defendant Allen will fairly and adequately represent the interests of the class.

IV. THE STATUTORY FRAMEWORK

20. The Act makes it a crime to provide mifepristone for the purpose of inducing an abortion except, “in accordance with all provisions of *federal law* that govern the use of RU-486 (mifepristone) for inducing abortions.” Ohio Revised Code § 2929.123 (A) (as amended by HB 126) (emphasis added).

21. The Act defines “federal law” as “a law, rule, or regulation of the United States or any drug approval letter of the food and drug administration [sic] of the United States that governs or regulates the use of RU-486 (mifepristone) for the purpose of inducing abortions.” *Id.* at § 2929.123 (F)(1).

22. The Act contains no exception for the health or life of the woman.

23. Violation of the Act is felony in the fourth degree, punishable by imprisonment for up to one and a half years or a fine of up to \$5,000, or both. Ohio Revised Code §§ 2929.14(A)(4) and 2929.18(A)(3)(d).

24. A physician who is convicted of violating the Act may also face professional discipline including license suspension or revocation. *See* Ohio Revised Code §§ 2919.123 (E)(as amended by the Act) and 4731.22. A physician who pleads guilty to, or is convicted of, a second or subsequent violation of the Act shall have his or her license suspended for at least one year. Ohio Revised Code § 4731.22 (C) (as amended by the Act).

25. Pursuant to Ohio law establishing accomplice liability, the plaintiff clinics and their employees, staff, servants, officers, or agents who solicit, request, command, encourage, or intentionally aid another person to engage in conduct that violates the Act could be prosecuted as accomplices. Ohio Revised Code § 2923.03.

26. The plaintiff clinics may also be prosecuted as corporations for the medical abortions performed by their employees or agents who are acting within the scope of their employment. Ohio Revised Code § 2901.23.

V. FACTUAL BACKGROUND

A. Mifepristone and Medical Abortion

27. Mifepristone, or RU-486 as it is commonly known, was approved by the FDA in 2000 for use in ending early pregnancy. Mifepristone allows women to terminate their pregnancies medically, rather than surgically, generally without any surgical intervention whatsoever.

28. At Plaintiffs' clinics, the patient ingests the mifepristone orally. After the mifepristone has taken effect, the patient then takes a second drug, misoprostol, that she generally inserts vaginally and which causes the woman to expel the products of conception.

29. Medical abortion requires no anesthesia or sedation whatsoever. Women most often take only over the counter medication to control any pain caused by the procedure.

30. Unlike with surgical abortion, medical abortion allows the patient to control to a great extent the timing and location of the completion of the procedure.

31. Since the approval of mifepristone, increasing numbers of women in Ohio, and across the United States, have chosen medical rather than surgical abortion to terminate a pregnancy early in the first trimester.

32. Most patients choose medical abortion because it is non-invasive and more private, and because it allows them to have more control over the procedure.

33. Additionally, many women prefer the medical procedure over the surgical one because they fear invasive surgery and anesthesia. Particularly for victims of rape, or for women who have experienced sexual abuse or molestation, medical abortion is often less traumatic because it is less invasive.

34. For some women who suffer from medical conditions such as an abnormality of the uterus, fibroids or cervical stenosis that make surgical abortion dangerous or impossible, medical abortion provides the only option for terminating a pregnancy in the first trimester. If these women cannot avail themselves of first-trimester medical abortion, their only alternative is to undergo a significantly more dangerous and invasive medical procedure, or forego abortion

and carry an unwanted pregnancy. Some of these women could have other health complications arising out of, or exacerbated by, their being forced to continue unwanted pregnancies. Such complications could threaten the life or the health of these women.

35. Women also choose medical abortion for physiological reasons. Surgical abortion can be extremely uncomfortable or painful for some women. Women who experience pain or extreme anxiety with surgical abortion are often given sedation for the procedure. The risks of sedation, however, are significant, and are indeed much greater than the risks of the first trimester surgical abortion itself. For such women, medical abortion may be medically indicated. In addition, women who are obese are at greater risks for complications from surgical abortion than women who are not obese and, therefore, medical abortion may also be indicated for obese women.

B. The FDA Approval Letter & Evidence-Based Use of Mifepristone

36. When the FDA approved mifepristone for use in the United States, it placed several restrictions on its distribution. These restrictions are set forth in the FDA letter approving mifepristone (the Approval Letter).

37. The Approval Letter requires that certain specific documents be used in conjunction with the sale and use of mifepristone. These documents, referred to collectively in the Approval Letter as the “final printed labeling (FPL),” include a Package Insert and Medication Guide to be given to each patient, a Patient Agreement Form to be executed by each patient, and the Prescriber’s Agreement to be executed by the prescribing physician.

38. While the Approval Letter does not require providers of mifepristone to adhere to any particular dosage or use regimen, the documents included in the final printed labeling discuss specifically and exclusively the dosage and use regimen that were used in the safety studies that formed the basis of the FDA approval.

39. The dosage and use regimen considered by the FDA, and set forth in the final printed labeling, limited use of mifepristone to pregnancies through 49 days LMP, and the patient was given a dosage of 600 mg (three pills) of mifepristone.

40. While the FDA approved mifepristone based a particular dosage and usage regimen, physicians are not required in their practice to adhere to this regimen.

41. It is standard medical practice with all FDA-approved drugs for physicians to use drugs in doses or contexts that were not specifically approved by the FDA so long as the alternative use is supported by adequate study. Such uses are sometimes referred to as “evidence-based” or “off-label” uses.

42. Many states, including Ohio, have recognized the importance of evidence-based uses of medications to the practice of medicine and patient care by, for example, prohibiting insurers that provide coverage for prescription drugs from denying coverage for a drug on the “basis that the drug has not been approved by the [FDA] for the treatment of the particular indication for which the drug has been prescribed.” Ohio Rev. Code § 1751.66 (A).

43. Since the studies that were used to obtain FDA approval of mifepristone, extensive medical research has conclusively established that mifepristone is safe and effective when given in lower dosages (200 mg rather than 600 mg), and later in pregnancy (to 63 days rather than to 49 days LMP).

44. Based on this research, it is now standard medical practice across the United States to provide medical abortion through 63 days of pregnancy (9 weeks LMP), and to use only 200 mg of mifepristone.

45. These evidence-based regimens have significant benefits for women.

46. First, noticeable signs of pregnancy often only emerge after 7 weeks LMP. Accordingly, the time-period between 7-9 weeks LMP is often when women discover they are pregnant and chose to have an abortion.

47. The evidence-based practice of using mifepristone up to 63 days LMP allows women who only discover they are pregnant or are only able to reach a clinic after 49 days LMP also to access the less invasive, and in some instances safer, procedure of medical abortion.

48. Second, providing the lower dose of mifepristone has a double benefit of reducing the amount of medication the woman must ingest, and reducing the cost of the procedure.

49. Mifepristone is sold in the United States in 200 mg pills. The manufacturer charges between \$80-\$90 for each pill. Thus, although the evidence-based regimen has been proven equally efficacious, the cost of the medication used for this procedure is at least \$160-\$180 less than the cost of the same procedure under the regimen considered by the FDA.

50. For these reasons, evidence-based use of mifepristone allows Plaintiffs to offer medical abortion to more of their patients and at a significantly lower cost than would be feasible under the regimen considered by the FDA.

VI. THE VAGUENESS OF THE ACT

51. The Act is vague as to the meaning of “federal law,” specifically whether the reference to the Approval Letter incorporates all of the other documents referenced in that letter and, if it does, whether all of the language in the other documents is “federal law” under the Act.

52. As a result, Plaintiffs are uncertain whether they can continue to provide medical abortion in accordance with the evidence-based regimen or whether the Act requires compliance with the usage regimen discussed in the final printed labeling for mifepristone.

53. Plaintiffs are left with the untenable dilemma of either ceasing to provide medical abortion in accordance with evidence-based regimens proven safe and effective by copious medical research published over the past decade, or continuing to provide access to a safe and effective method of early abortion to their patients under the risk of possible criminal prosecution and loss of their medical licenses.

VII. THE EFFECT OF THE ACT ON WOMEN’S ACCESS TO ABORTION AND ADEQUATE MEDICAL CARE

54. A prohibition on evidence-based use of mifepristone would violate patients’ right to bodily integrity and right to choose abortion.

55. If the Act limits medical abortion to the dosage regimen used in the FDA trials, then Plaintiffs’ patients up to 7 weeks LMP would be forced to pay significantly more for a medical abortion and to ingest unnecessarily large amounts of medication.

56. For many women, particularly minors and indigent women, this increased cost of medication would place medical abortion financially out of their reach.

57. In addition, if the Act limits medical abortion to the dosage regimen used in the FDA trials, then after 7 weeks LMP Plaintiffs' patients would be forced to undergo surgery and anesthesia when a less invasive, viable medical alternative would otherwise be available to them that would allow them to exercise a significant amount of control over their bodies.

58. A prohibition on the practice of evidence-based medicine in provision of mifepristone would also dangerously limit Plaintiffs' discretion to use the best and safest medical procedures for their patients based on their individual circumstances and medical conditions.

59. If the Act limits medical abortion to the dosage regimen used in the FDA trials, then the Act fails to meet the constitutional requirement that any restriction on a method of abortion contain an exception to protect the life and health of the woman.

60. If the Act limits medical abortion to the dosage regimen used in the FDA trials, then women who suffer from a condition that precludes surgical abortion, and whose life or health became seriously threatened by a pregnancy after 7 weeks LMP, will be placed in the untenable position of choosing between undergoing a significantly more dangerous procedure, or continuing pregnancy in the face of unknown risks and health concerns.

61. If the Act limits medical abortion to the dosage regimen used in the FDA trials, then it would prohibit Plaintiffs from providing a common, readily available, and safe method of terminating a pregnancy between 7 and 9 weeks LMP.

VIII. INJUNCTIVE RELIEF

62. Plaintiffs have no adequate remedy at law and will suffer irreparable harm of continued violations of their and their patients' constitutional rights if the Act goes into effect.

63. Enforcement of the Act will cause irreparable harm by threatening Plaintiffs with criminal prosecution and civil liability for providing, participating in, assisting in, or supervising the provision of mifepristone, thereby chilling the provision of those services; preventing some patients from receiving medical abortion services in the first trimester even when those services

are necessary to preserve the life or the health of the woman; forcing some women to have a surgical abortion that is more invasive and less private than an otherwise available, equally safe and effective method; greatly increasing the cost of obtaining medical abortions; and depriving women of their right to determine, together with their physicians, the course of their own medical treatment.

CLAIMS FOR RELIEF

COUNT I – RIGHT TO DUE PROCESS OF LAW

64. Plaintiffs hereby reaffirm and reallege each and every allegation made in ¶¶ 1-63 above as if set forth fully herein.

65. The Act violates the rights of Plaintiffs and their employees and agents to due process as guaranteed by the Fourteenth Amendment to the United States Constitution because it is impermissibly vague, fails to give adequate notice of the procedures it proscribes, and encourages arbitrary enforcement.

COUNT II – RIGHT TO DUE PROCESS OF LAW

66. Plaintiffs hereby reaffirm and reallege each and every allegation made in ¶¶ 1-63 above as if set forth fully herein.

67. The Act violates Plaintiffs' patients' right to bodily integrity guaranteed by the Due Process Clause of the Fourteenth Amendment by depriving them of access to a medically accepted abortion procedure of their choice, and by forcing them to undergo abortion procedures that are more invasive, less private, and sometimes more painful or dangerous than those banned by the Act.

COUNT III – RIGHT TO DUE PROCESS OF LAW

68. Plaintiffs hereby reaffirm and reallege each and every allegation made in ¶¶ 1-63 above as if set forth fully herein.

69. The Act violates the right of Plaintiffs' patients to privacy as guaranteed by the Fourteenth Amendment to the United States Constitution because it does not contain an exception for the life or health of the patient.

COUNT IV – RIGHT TO DUE PROCESS OF LAW

70. Plaintiffs hereby reaffirm and reallege each and every allegation made in ¶¶1-63 above as if set forth fully herein.

71. The Act violates the rights of Plaintiffs' patients to privacy as guaranteed by the Fourteenth Amendment to the United States Constitution by imposing an unconstitutional burden on their right to abortion.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

1. A preliminary injunction, and a permanent injunction restraining Defendants, their employees, agents, and successors from enforcing the challenged Act;
2. A declaration by this Court that the challenged Act is in violation of the United States Constitution and cannot be enforced;
3. For reasonable attorneys' fees and costs incurred in prosecuting this action, pursuant to statutory and common law; and
4. For such other and further relief as this Court finds just and equitable.

Dated this 14th day of September, 2004.

Respectfully submitted,

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Attorneys for Plaintiff Preterm

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2004 a copy of the foregoing pleading was filed electronically. Notice of this filing will be sent to all parties for whom counsel has entered an appearance by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. I further certify that a copy of the foregoing pleading and the Notice of Electronic Filing has been served by ordinary U.S. mail upon all parties for whom counsel has not yet entered an appearance electronically.

/s/ Nicole G. Berner
Attorney for Plaintiffs